FEB 18 2004

K 033978

2 510 (K) Summary

This summary is submitted in accordance with the requirements of 807.92. This summary was prepared on Dec 11, 2003

Submitted By: Grass-Telefactor Product Group
Astro-Med, Inc.
600 East Greenwich Ave
West Warwick, RI 02893
Tel: (401) 828-4000
Fax: (401) 822-2480

Contact Person: Michael J. Sullivan
VP Engineering
Tel: 401-828-4000 x212
Email: msullivan@astromed.com

Proprietary Name : ADAM

Common Name: EEG Amplifier System

Product Category: Electroencephalograph
Regulation number: 882.1400
Medical Speciality: NE
Product Code: GWQ
Product Class: Class II Device

This device claims substantial equivalence to the following:

Telefactor H2O: 510(k) numbers K992291 and K974587
Grass – Telefactor AS-40 Amplifier System 510(k) number K021807

Intended Use:
The ADAM amplifier system is intended for recording routine EEG and EEG associated with long term monitoring for epilepsy. This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in electroencephalography.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

Mr. Michael J. Sullivan
Vice President of Engineering
Grass-Telefactor Product Group
Astro-Med, Inc.
600 East Greenwich Avenue
West Warwick, Rhode Island 02893

Re: K033978
Trade/Device Name: Grass-Telefactor ADAM
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: December 19, 2003
Received: January 5, 2004

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033978

Device Name: Grass-Telefactor ADAM

Indications For Use:

The ADAM amplifier system is intended for recording routine EEG and EEG associated with long term monitoring for epilepsy.
This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in electroencephalography.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033978